

## REMARKS

An Office Action was mailed in the above-captioned application on May 15, 2007. In such Office Action claims 1-3, 5, and 7-12 were pending. Claims 1-3, 5, and 7-12 were rejected. This Amendment and Remarks document is submitted in response to said Office Action.

### The Rejection under 35 U.S.C. § 112, first paragraph

The Examiner has rejected claims 1-3, 5 and 8-12 under 35 U.S.C. § 112, first paragraph as containing subject matter which does not comply with the enablement requirement.

The first paragraph of § 112 requires that a patent application be written so as to “enable any person skilled in the art to which it pertains . . . to make and use the same.” A specification is presumed to be enabling absent “a reason to doubt the objective truth of the statements contained therein.” *In re Marzocchi*, 169 USPQ 367, 369 (C.C.P.A 1971). Further, a specification “may be enabling even though some experimentation is necessary,” *United States v. Teletronics, Inc.*, 857 F.2d 778, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988), so long as the amount of experimentation required is not “undue experimentation.” *In re Wands*, 858 F. 2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). The test is whether the specification “provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.” *In re Wands*, 858 F. 2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Specifically, the rejection states that the rejection is withdrawn over amended claim 7, limited to a C57BL/6 X SJL transgenic mouse, in view of the amendments to claim 1, but that the rejection is maintained in part for claims 1-3, 5 and 8-12.

Applicant does not acquiesce in this rejection for the reasons made of record in previous submissions; however, solely in the interest of expediting prosecution, Applicant has amended claims 1-3 to include the recitation of claim 7, and claims 1-3 now recite a C57BL/6 X SJL transgenic mouse. Accordingly, Claim 7 has been cancelled. In view of this amendment, Applicant requests reconsideration of the rejection under 35 U.S.C. § 112, first paragraph as lacking enablement.

The Rejection under 35 U.S.C. § 103(a)

The Examiner has rejected Claims 1, 2, 5 and 7-9 under 35 U.S.C. § 103(a) as being unpatentable over McKenzie, et al., (1999), *J. Immunol.* 162:4311-4318. The Examiner bears the burden of establishing a prima facie case of obviousness (Section 103). In determining obviousness, one must focus on Applicant's invention as a whole. *Symbol Technologies Inc. v. Opticon Inc.*, 19 U.S.P.Q.2d 1241, 1246 (Fed. Cir. 1991).

The rejection states that the rejection is maintained for the reasons of record. Applicant does not acquiesce in this rejection for the reasons made of record in previous submissions; however, solely in the interest of expediting prosecution, Applicant has amended claim 1 to include the recitation of claim 10, which is not rejected under this section. Claim 1 now recites that autoimmune disease is selected from the group consisting of arthritis and systemic lupus erythematosus. Accordingly, Claim 10 has been cancelled. In view of this amendment, Applicant requests reconsideration of the rejection under 35 U.S.C. § 103(a).

Closing Remarks

Applicant believes that the pending claims are in condition for allowance. If it would be helpful to obtain favorable consideration of this case, the Examiner is encouraged to call and discuss this case with the undersigned.

This constitutes a request for any needed extension of time and an authorization to charge all fees therefore to deposit account No. 19-1970, if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to deposit account No. 19-1970.

Respectfully submitted,

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